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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/766,154

Applicant(s)

Patience

Examiner

Anne Marie Wehbé

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 16, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25, 28-32, 34-41, and 43-52 is/are pending in the application.
- 4a) Of the above, claim(s) 1-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-32, 34-41, and 43-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

Applicant's amendment and response received on 12/16/02 has been entered. Claims 26, 27, 33, and 42 have been canceled. New claims 45-52 have been added. Claims 1-25, 28-32, 34-41, and 43-52 are pending in the instant application. Of these, claims 1-25 have been withdrawn as being drawn to subject matter non-elected with traverse in paper no.7. This application contains claims 1-25 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 28-32, 34-41, and 43-52 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code not included in this action can be found in the previous office action.

### ***Claim Rejections - 35 USC § 112***

The rejection of previously pending claims 27-44 under 35 U.S.C. 112, first paragraph, for lack of written description is maintained in part over pending claims 28-32, 34-41, and 43-52.

Please note that claims 45-52 are product by process claims and thus are properly included in this

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rejection. Applicant's arguments and claim amendments have been fully considered but have been found unpersuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

Applicant's amendment of the claims to recite PERV rather than ERV has overcome the lack of written description for ERV other than porcine ERV.

In regards to the remaining grounds for rejection for lack of written description, applicant's attention is drawn to the fact that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. The applicant has not specifically addressed the issues raised under lack of written description in the previous office action. These issues include the lack of written description for animals other than pigs which are human-tropic PERV-positive, and the lack of written description for PERV loci or oligonucleotide primers or probes capable of detecting human-tropic PERV loci other than type-c PERV loci. The previous office pointed out that the specification provides no description of any animal species which naturally contains human-tropic PERV other than swine. The previous office actions also discusses the fact that the specification provides no guidance as to the sequences of any PERV other than type C PERV, or provide any description of oligonucleotides which are capable of recognizing and binding PERV loci from any and all species of animals. The applicant has not addressed either of these issues. Therefore, the rejection of record is maintained.

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The rejection of previously pending claims 28-44 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained in part over pending claims 28-32, 34-41, and 43-52. As noted above, claims 45-52 are product by process claims and are therefore properly included in this rejection. Applicant's arguments and claim amendments have been fully considered but have been found unpersuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The specification, while being enabling for a process of producing a human-tropic PERV free pig from parental pigs wherein at least one parental pig is human-tropic PERV positive comprising: a) determining the number of human-tropic PERV in a male pig and a female pig, b) mating a male and a female pig wherein the male and female pigs are positive for at least one PERV locus and negative for different PERV-loci thereby producing offspring, c) selecting offspring which are free of at least one human tropic PERV loci, and d) repeating step a) with the offspring of step c), and e) selecting the offspring of step d) which are free of human tropic PERV, does not reasonably provide enablement for processes of producing any animal which is free of any type of human-tropic PERV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The applicant argues that methods of mating animals are well known in the art and that swine breeding programs are readily adaptable to other species. The office has not stated or suggested that methods of mating and breeding animals other than swine is not enabled. The lack

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of enablement in the instant invention lies in the lack of guidance for animals other than pigs which are human-trophic PERV positive. As discussed above, the specification fails to provide sufficient guidance as to animals other than pigs which contain human-tropic porcine endogenous retroviruses. Applicant's methods require the mating of a parental animal which is human-trophic PERV positive with a parental animal which is human-trophic PERV negative. PERV is an endogenous retrovirus specific for pigs. While the prior art speculates that certain PERV are capable of infecting human cells, the prior art does not teach any animal species which contains PERV other than swine. Thus, the specification does not enable the use of animals other than swine in the instant methods because neither the specification for the prior art of record teaches or suggests that PERV can be found in other animal species such as dogs, cats, or fish.

The applicant is also reminded that case law states that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). Furthermore, the Federal Circuit has stated that:

a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.** It is the

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specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.  
Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

Thus, by failing to identify animals other than pigs which naturally carry human-tropic PERV, the specification fails to meet the enablement requirement for how to make and use the invention as claimed.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, for indefiniteness is withdrawn in view of applicant's amendment.

The rejection of claims 39-44 under 35 U.S.C. 112, second paragraph, for indefiniteness is withdrawn in view of applicant's amendments to the claims.

### ***Claim Rejections - 35 USC § 102***

The rejection of canceled claims 26-27 under 35 U.S.C. 102(b) as being anticipated by Kaeffer et al. is maintained over new claims 45-52. The applicant claims inbred miniature swine of DD haplotype which are inbred so as to remove infectious PERV gene sequences from the genome thereof, and which have been produced by a particular mating and screening process.

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Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the human-trophic PERV free DD haplotype miniature swine are produced by a specific breeding process not taught by Kaeffer et al. Applicant's new claims are indeed product by process claims. However, the applicant is reminded that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The previous office action stated that Kaeffer et al. teaches miniature DD haplotype swine, and that the applicant states in their specification that the miniature DD haplotype swine does not naturally contain human-trophic PERV (specification, page 18, Table 2, page 28, Table 4). The lack of human trophic PERV appears therefore to be an inherent property of the miniature DD haplotype swine. Thus, the product of the art and the product of the instant invention have the same structure, a miniature DD haplotype swine which is human-trophic PERV negative. Furthermore, the MPEP states that, when the claimed and prior art products are identical or substantially identical in structure, a *prima facie* case of either anticipation has been established. MPEP 211.01 and *In re Best*, 195 USPQ 430, 433 (CCPA 1997).

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It is also noted that “When the PTO shows a sound basis for believing that the products of th applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). The office does not have the facilities for examining and comparing applicant’s product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). The applicant has not provided any evidence that the DD haplotype miniature swine taught by Kaeffer et al. contain human trophic PERV. Therefore, the rejection of record is maintained.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

